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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,669	06/01/2000	Edward Moacrieff Sellers	064658.0139	4778

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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/584,669

**Applicant(s)**

SELLERS ET AL.

**Examiner**

Michael V. Meller

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 24-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group III in Paper No. 8 is acknowledged. The traversal in paper number 11 is in addition to the one presented in paper number 8 which is on the ground(s) that the examiner did not properly restrict the kit (claim 24) from the method for enhancing the effectiveness of nicotine replacement therapy (claims 22 and 23). This is not found persuasive because the examiner has given a proper use for the kit (composition) other than the use in claims 22 and 23. The examiner has followed the MPEP in that a materially distinct use was given for the kit of claim 24. Applicants' arguments has no merit because a proper restriction has been made since a materially distinct and different process has been given for using the kit of claim 24.

Claims 1-21 and 24-34 remain withdrawn by the examiner as being drawn to non-elected subject matter.

This application contains claims 1-21 and 24-34 which are drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The requirement is still deemed proper and therefore remains FINAL as was made in paper number 9.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

The specification remains objected to since Tables 2-5 appear in the specification before Table 1. Since this is not logically correct, it is object to in the instant specification.

### ***Claim Rejections - 35 USC § 103***

Claims 22 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viner for the reasons of record and for the reasons which follow.

Applicants' claims are drawn to a method for enhancing the effectiveness of nicotine replacement therapy. Viner teaches a method for controlling tobacco use and alleviating withdrawal symptoms due to the cessation of tobacco use.

Both the instant invention and Viner teach that tobacco use is not healthy and desire to assist in helping the consumer discontinue use of tobacco. Both references administer the same composition, nicotine and pilocarpine, see claim 11 and 12. The only reason that Viner is not a 35 USC 102 reference against the instant claims is

because claim 11 teaches that to administer mixtures thereof of a markush group including nicotine and pilocarpine. Since the markush group is only of 10 members and since claim 11 explicitly states, "and mixtures thereof" gives an explicit teaching to one of ordinary skill in the art to use mixtures which would include nicotine and pilocarpine.

Applicant argues that Viner focuses on acetylcholine and makes no mention of the importance of mitigating the degradation of nicotine or reducing the production of procarcinogenic compounds but it is clear from Viner that he was aware of the fact that tobacco use is unhealthy and needs to be stopped. Viner recognizes that a "replacement" is needed in order to get a person off the use of tobacco as applicants are doing. Viner administers the same composition to a patient just as the invention does.

Applicant's next argument is that the composition of Viner is an oral one but applicants claims encompass an oral composition. Further, applicants also disclose use of an oral composition of their invention at page 6 of the instant specification, thus applicants comments are moot.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller  
Examiner  
Art Unit 1651

MVM  
June 24, 2002